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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/799,324	03/12/2004	Peter J. Connolly	JJPR-0035	8354

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EXAMINER

DAVIS, BRIAN J

ART UNIT PAPER NUMBER

1621

DATE MAILED: 09/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/799,324

Applicant(s)

CONNOLLY ET AL.

Examiner

Brian J. Davis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-235 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) See Continuation Sheet is/are allowed.
- 6) ☒ Claim(s) See Continuation Sheet is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5/21/04</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims allowed are 14-24,31-41,48-58,65,83-93,100-110,117-127,134-144,151-161,168-178,185-195 and 202-212.

Continuation of Disposition of Claims: Claims rejected are 25-30,42-47,59-64,66-82,94-99,111-116,128-133,145-150,162-167,179-184,196-201 and 213-235.

DETAILED ACTION

Information Disclosure Statement

As stated in the previous Office Action, the examiner notes for clarity of the record that there are cover sheets in the application for an IDS of record on 9/24/04, **but not the IDS itself**. The examiner respectfully requests that this IDS be included in applicant's next correspondence with the Office. The first IDS, the IDS of record on 5/21/04, is complete. An initialed copy of this IDS is attached.

Claim Objections Withdrawn

The objection to claims 22, 30, 39, 47, 56, 64, 74, 82, 91, 99, 108, 116, 125, 133, 142, 150, 159, 167, 176, 184, 193, 201, 210, 218, 227 and 235, outlined in the previous Office Action, has been overcome by applicant's amendment. The amendment corrects the claim text as appropriate.

112 Rejections Withdrawn

The rejection of claims 85-93 and 219-235 under 35 USC 112, second paragraph, outlined in the previous Office Action, has been overcome by applicant's amendment. With specific regard to claims 85 and 219, the amendment clarifies the claim text as appropriate. With regard to the remaining claims, the rejection is moot.

112 Rejections Maintained

The rejection of claims 25, 42, 59, 77, 94, 111, 128, 145, 162, 179, 196, 213 and 230 under 35 U.S.C. 112, second paragraph, outlined in the previous Office Action, is maintained for reasons of record. Applicant's amendment and arguments have been carefully considered, but are not persuasive.

The instant phrase "...compound comprising the formula of claim 14..." is equivalent to the phrase rejected previously: "...compound comprising a compound...". That is, the formula of claim 14 is a compound. The examiner respectfully points out that a compound cannot be anything other than itself and therefore cannot logically be described with the "open" language of "comprising." The examiner respectfully suggests a slight rewording, something along the lines of: "An oral composition comprising an EPO receptor modulating compound of formula 14..."

Claims 26-30, 43-47, 60-64, 78-82, 95-99, 112-116, 129-133, 146-150, 163-167, 180-184, 197-201, 214-218 and 231-235 also remain rejected under 35 USC 112, second paragraph, as claims which depend from indefinite claims are also indefinite. *Ex parte Cordova*, 10 USPQ 2d 1949, 1952 (PTO Bd. App. 1989).

Double Patenting Rejections Maintained

The rejection of claims 66-82 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 6,750,369, outlined in the previous Office Action, is maintained for reasons of record. While applicant states in the remarks accompanying the amendment that a

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Terminal Disclaimer has been submitted, none is of record in the application. This does not appear to be a PTO error, since even applicant's Reply Transmittal Letter accompanying the amendment indicates that no Terminal Disclaimer was submitted (the appropriate box is left unchecked).

102 Rejections Withdrawn

The rejection of claims 219-235 in so far as they read on the species defined in the previous Office Action under 35 USC 102(b) has been overcome by applicant's amendment. The amendment narrows the definition of substituent R⁴ such that the claims no longer read on the cited prior art.

Allowable Subject Matter

Claims 14-24, 31-41, 48-58, 65, 83-93, 100-110, 117-127, 134-144, 151-161, 168-178, 185-195 and 202-212 are allowed. Claims 25-30, 42-47, 59-64, 77-82, 94-99, 111-116, 128-133, 145-150, 162-167, 179-184, 196-201 and 213-218 would be allowable once the 112 rejections maintained above have been overcome. Claims 66-82 would be allowable upon the submission of an acceptable Terminal Disclaimer.

The search was therefore expanded as called for under current Office Markush practice, a compound-by-compound search, to include a single additional compound from the Markush group described in claims 219-235. That species is defined when: R¹⁻³ = H and R⁴ = benzyl (side chain of phenylalanine). A rejection follows:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 219-235, in so far as they read on the species defined above, are rejected under 35 U.S.C. 103(a) as being unpatentable over *Journal of Chemical*

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Research, Synopses (1978), (2), p. 80-81 (CAPLUS abstract) and further in view of *Yakugaku Zasshi* (1978), 98(7), p. 869-879 (CAPLUS abstract).

Applicant's species has been defined above.

Journal of Chemical Research, Synopses (1978), (2), p. 80-81 teaches the racemate of this species.

Yakugaku Zasshi (1978), 98(7), p. 869-879 teaches the L enantiomer of the above racemate.

Applicant distinguishes over the prior art in that the D enantiomer is claimed. However, this enantiomer would have been obvious to one of ordinary skill in the art at the time of the invention given that the racemate and the L enantiomer are old and well-known. The claimed compound is simply the remaining stereoisomer.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any


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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Davis whose telephone number is 571-272-0638. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


BRIAN DAVIS
PRIMARY EXAMINER
Brian J. Davis
August 30, 2005